

## **Information for Parents**

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Infants in California are screened for a wide variety of genetic disorders at birth, most of which, if found early and treated, can prevent mental retardation, severe neurological problems, irreversible comas, and even death. Currently, approximately 1 in 600 births are diagnosed with one of the disorders screened for by the Genetic Disease Screening Program (GDSP). GDSP also provides important follow-up services for infants that are identified through this public health screening program. This follow-up ensures timely medical care which has been documented to dramatically improve the health of children that have one of these disorders.

The GDSP is required by state and federal laws, to keep information about the samples private. They are stored in a highly secured building. The actual sample card has only an assigned number and no other information about the baby. Only authorized GDSP staff has access to the information that was provided to the GDSP so that we can interpret and report out the newborn screening test result to the newborn's pediatrician and hospital of birth.

There are several reasons why the newborn specimen card is stored by the GDSP:

1. To have a large number of de-identified (anonymous) specimens to use to develop tests for new disorders. It can take up to 100,000 "practice" samples for GDSP to develop a new screening test for a new disorder.
2. Using specimens that come from California is very important. The use of these samples has let GDSP develop new tests and to improve the screening program. Using the information (race/ethnicity) of California babies allow GDSP to improve the correctness of the test.
3. The baby's screening test can be repeated if needed without getting another blood sample from the baby.
4. The baby's sample is properly stored and available to parents for other health-related testing (for example, in the case of unexplained deaths such as Sudden Infant Death Syndrome (SIDS), or the specimen is required to check for a rare disorder).
5. The baby's sample is available to parents to help identify a missing or deceased child.

Samples that have personal identifying information are never released to researchers or outside agencies without prior approval of the parents (for example, in the case of a formal research study, where the parent signs a consent for the researcher to use their baby's sample). The GDSP adheres to all rules regarding human subjects research as described by State and Federal law. The Program does not store the sample to gather DNA on babies. The samples are not provided to any state or national forensic DNA data banks.

The GDSP takes these confidentiality requirements extremely seriously and there are severe penalties for the unlawful release of any information that identifies a parent or infant. These penalties include significant fines and other financial penalties, and possible jail time. Since the start of this program, there has never been an instance of a privacy breach.

The GDSP considers the use of these samples an invaluable resource, without which the addition and improvement of testing for specific disorders would have been delayed significantly; resulting in sick newborns not receiving timely medical care. California is considered a national leader in newborn screening and use of the dried blood samples has been a large part of our success. This screening program benefits all California newborns, families and the communities in which they live.